

K050681

JUL 27 2005

1/2

510(K) Summary of Safety and Effectiveness
OMNITECH and EASY LOCK OSTEOSYSTEM

Submitted By: TriMed, Inc.
25768 Parada Drive
Valencia, CA 91355
(800)633-7221

Registration #: 2031009

Manufactured By: Biotech International
305, Allées de Craponne
13300 Salon de Provence, France
Phone: (33)4 90 44 60 60
Fax: (33)4 90 44 60 61

Manufacturer's Registration #: K050681

Prepared By/Contact Person: Kelli Anderson
Phone: (661) 312-7150
Fax: (661) 254-8485

Proprietary Name: Omnitech
Easy Lock Osteosystem with
Xtremities Plates

Classification: Class II: Plate Fixation Bone
Section 888.3030
Screw Fixation Bone
Section 888.3040

Classification Code: HRS
HWC

Summary Preparation Date: June 3, 2005

Intended Use:

Omnitech System:

The Omnitech Small Fragment Osteosynthesis System is intended for use in the internal fixation of small bones in the hand and foot.

EasyLock Osteosystem & Xtremities:

1050681

2/2

The Easy Lock and Xtremities implants may be used for permanent or temporary osteosynthesis of small bones, tarsal and carpal fractures, and for the fixation of osteotomies or arthrodesis.

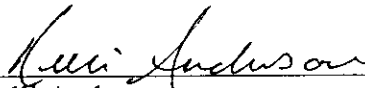
Substantial Equivalence:

Omnitech

K991964 - Lepine EIS Threaded Screws for Metatarsal Fixation
K792022 - Zimmer Herbert Bone Screw
K021626 - Newdeal Hallu Plates
K001941 - Synthes Modular Foot System
K961941 - Howmedica Profyle Hand & Small Fragment System

Easy Lock

K021626 - Newdeal Hallu Plates
K961941 - Howmedica Profyle Hand & Small Fragment System (Now Stryker Leibinger)
K991873 - KMI Wrist Fusion System
K021321 - Acumed Wrist Fusion Plate



Kelli Anderson
Regulatory Affairs Specialist



JUL 27 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kelli Anderson
Regulatory Affairs Specialist
TriMed, Inc.
25768 Parada Drive
Valencia, California 91355

Re: K050681

Trade/Device Name: Omnitech[®] System EasyLock Osteosystem & Xtremities
Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories, Smooth or threaded metallic bone
fixation fastener
Regulatory Class: II
Product Code: HRS, HWC
Dated: June 7, 2005
Received: June 9, 2005

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

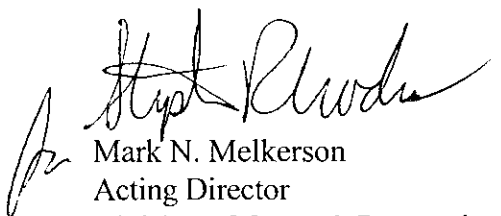
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050681

Device Name: Omnitech® System
 EasyLock Osteosystem & Xtremities

Indications For Use

Omnitech System:

The Omnitech Small Fragment Osteosynthesis System is intended for use in the internal fixation of small bones in the hand and foot.

EasyLock Osteosystem & Xtremities:

The Easy Lock and Xtremities implants may be used for permanent or temporary osteosynthesis of small bones, tarsal and carpal fractures, and for the fixation of osteotomies or arthrodesis.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050681

Page 1 of 1